



Die

PTO/SB/64 (10-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT  
ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)**

Docket Number (Optional)

First named inventor: NEHRING, et al.

Application No.: 10/022,406

Art Unit: 1743

Filed: 20 DECEMBER, 2001

Examiner: ARLENSODERQUIST

Title: TRANSPORT SYSTEM FOR PRODUCTS AT  
CONSISTENT TEMPERATURES

Attention: Office of Petitions  
Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the office notice or action plus an extensions of time actually obtained.

**APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION**

NOTE: A grantable petition requires the following items:

- (1) Petition fee;
- (2) Reply and/or issue fee;
- (3) Terminal disclaimer with disclaimer fee - required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
- (4) Statement that the entire delay was unintentional.

**1. Petition fee**

☒ Small entity-fee \$ 225 (37 CFR 1.17(m)). Applicant claims small entity status. See 37 CFR 1.27.

☐ Other than small entity - fee \$ \_\_\_\_\_ (37 CFR 1.17(m))

**2. Reply and/or fee**

A. The reply and/or fee to the above-noted Office action in the form of PETITION FOR THE REVIVAL (identify type of reply): 37CFR1.181

☒ NOTICE OF ABANDONMENT 20 MAY 2005  
☒ has been filed previously on \_\_\_\_\_  
☒ is enclosed herewith.

B. The issue fee and publication fee (if applicable) of \$ 1500.

☐ has been paid previously on \_\_\_\_\_  
☒ is enclosed herewith.

[Page 1 of 2]

This collection of information is required by 37 CFR 1.137(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

04/11/2006 RWDNAF1 00000028 10022406

04 FC:2453

750.00 OP

## 3. Terminal disclaimer with disclaimer fee

- ☐ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.
- ☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of \$ \_\_\_\_\_ for a small entity or \$ \_\_\_\_\_ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

**WARNING:**

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

*D. Neuring*  
Signature

5 APRIL 2006  
Date

DIRK NEHRING  
Typed or printed name

Registration Number, if applicable

DELTA T GMBH, KERKRADER STR 11 +49/641 4809240  
Address Telephone Number

35394 GIESSEN, GERMANY  
Address

Enclosures: ☒ Fee Payment

☒ Reply

☐ Terminal Disclaimer Form

☒ Additional sheets containing statements establishing unintentional delay

☐ Other: \_\_\_\_\_

**CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]**

I hereby certify that this correspondence is being:

☐ Deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

☒ Transmitted by facsimile on the date shown below to the United States Patent and Trademark Office as (571) 273-8300.

5 APRIL 2006  
Date

*D. Neuring*  
Signature

Typed or printed name of person signing certificate

5 APRIL 2006

DIRK NEHRING



delta T GmbH Kerkrader Strasse 11 D-35394 Giessen

United States Patent and Trademark Office

Customer Service Window, Mail Stop

Randolph Building

401 Dulany Street

Alexandria, VA 22314

UNITED STATES of AMERICA

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Gesellschaft für  
Medizintechnik mbH

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Contact Person:

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E-Mail: [nehring@deltaT.de](mailto:nehring@deltaT.de)

Date: 4/05/2006

RENEWED PETITION UNDER 37 C.F.R. § 1.137(b)

FAX TO Petitions Department; 001 571 273-8300

PATENT APPLICATION NO: 10/022,406

FILING DATE: 12/20/2001

GROUP ART UNIT: 1743

EXAMINER: Mr Arlen Soderquist

DATE: 04/05/2006

Dear Sirs

We believe that we have correctly filled out all of the necessary forms and enclosed the appropriate payments to revive the above patent application. Our petition was abandoned as it seems that we did not make a timely payment in 2004. We did however fax a payment mandate with our credit card details to your offices on November 2nd 2004, a copy of our faxed sent items is attached herewith, which shows that this was in fact done. Clearly this did go unfortunately amiss, whether due to a technical fault or something that we feel was beyond our control. We naturally assumed due to our fax print out that your offices had received this mandate and that the payment was in fact made in a timely manner. We were not aware that the US Patent Office does not accept such proof. As we are now aware of this, we have sent these documents by courier to ensure your receipt of them. We realise that you must have millions of applications to work on and of course cannot be responsible for the failure of faxed items. Therefore, we would very much appreciate it if you would review our petition for the revival of our patent application given the misfortunate circumstances beyond both of our control.

In order to revive our application we have made the following payment mandates as follows;

- a) Small entity fee as we are below 5 employees \$ 225
- b) Issue fee according to 35u.s.c.41 (a7) \$ 1,500
- c) Open filing fee for the patent application \$ 161

We trust that these payments are correct and that they will secure our petition for revival. We were however unsure about the fees listed under point 3 of the form 37 CFR 1.137(B) as attached with regard to the "Terminal Disclaimer Fee". We understand that this does not apply to our petition. If however it does, could we request that you let us know by email to [nehring@deltaT.de](mailto:nehring@deltaT.de) or by calling us on +49 641 480 9240 to let us know. We will however follow this petition for revival up ourselves on April 10th 2006.

Thank you in advance for your assistance and we will look forward to hearing from you.

Kind regards,

Dirk Nehring

04/11/2006 AWONDAF1 00000028 10022406

01 FC:2202

02 FC:2203

03 FC:1461

75.00 OP  
180.00 OP  
131.00 OP

Bankverbindung:

Sparkasse Gießen

BLZ: 513 500 25

Kto.-Nr.: 241 023 700

Ust-IdNr.: DE209251853

Steuer Nr.: 020 231 21779

Sitz der Gesellschaft: Gießen HRB 3532

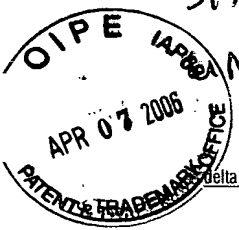
Geschäftsführer: Manfred Zorn, Dirk Nehring

Additional Sheet containing statement establishing unintentional delay:

Since we believe, that the payment according to Application number 10/022,406 was correct the failure to reply timely and properly to the 23 June, 2004, Office action was unintentional. We believed that our first calculation and transfer of the fees by credit card was correct so that the payment of the additional fee, which was claimed in the 23 June, 2004, Office action was delay and finally not processed.

Please refer also to our statement in the first petition.

ADDITIONAL SHEETS CONTAINING  
STATEMENTS ESTABLISHING  
UNINTENTIONAL DELAY



Delta T GmbH Kerkraeder Strasse 11 D-35394 Giessen

# delta T

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Ihr Ansprechpartner:

Dirk Nehring

E-mail: [nehring@deltaT.de](mailto:nehring@deltaT.de)

Date: Mittwoch, 1. Juni 2005

FAX TO: Petitions Department 001 703 872 9306

PATENT APPLICATION NO: 10/022,406 DeltaT GmbH

FILING DATE: 12/20/2001

GROUP ART UNIT: 1743

EXAMINER: Mr Arlen Soderquist

DATE: 05/31/2005

REFERENCE: Petition for the Revival of US Patent Application Form 37 cfr.1.181

Dear Sirs



We received notification today that our patent application has been abandoned due the non payment of fees of \$140 for multiple dependent claims and \$21 for excess claims. Following your request for the payment of these fees we sent you a fax on 11/02/2004 making the full payment of \$161 with your credit card payment form (please see attachment). We did therefore assume that payment had been made especially as the delivery status of our fax confirmed that the fax had been received by yourselves.

Unfortunately for some reason however this payment was not processed by your finance office. We have attached a copy of the delivery status of the fax from which the payment form was sent. Please excuse the fact that we can only provide this along with multiple other faxes that were sent also during that period as this is the only option we have to produce such a report from our computer system. Please also excuse the fact that it is also in German, again for obvious reasons. To explain however, the fax sent to you is 8<sup>th</sup> from the top sent at 11.25 which can be seen under 'Datum' =Date. Under the 2<sup>nd</sup> column 'Rufnr/Kennung' = Fax number it was sent to, you will see that it was sent to 703 305 8007. The last 4 columns show a) 'Dauer' = transfer time b) 'S' =Pages c) 'Gebühr' =Charge (in Euros) d) 'Status' =Status (of whether sent or not). You will see from the delivery report of the fax sent to you that 3 pages were sent, at a charge of €1.92, that the delivery was confirmed by 'Versand' =Sent and that the transfer took 7min 24 sec at 11:26 a.m. central European time.

We therefore request that you accept our petition to request the revival of our patent application as we reasonably assumed that our payment had been processed by your finance office.

We will look forward to reply and naturally will authorise another payment as soon as you direct us to do so.

Kind regards

   
Dirk Nehring Mark Brannon

Bankverbindung:

Sparkasse Gießen

BLZ: 513 500 25

Kto.-Nr.: 241 023 700

Ust-IdNr.: DE209251853

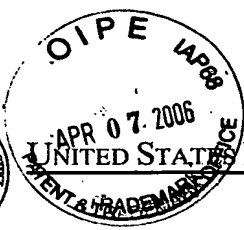
Steuer Nr.: 020 231 21779

Sitz der Gesellschaft: Gießen HRB 3532

Geschäftsführer: Manfred Zorn, Dirk Nehring



Datum	Rufnr./Kennung	Teilnehmer	Bemerkung	Start	Dauer	S.	Gebühr	Status
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Mi. 10.11.2004, 12:33:56	61 2 9848 1123		Scan	12:34:22	01:15	1	3,12	Versandt
Mi. 10.11.2004, 10:29:18	+49 2953 7241	Radke; Transmed S	z. Hd. Dirk Radke !!	10:29:24	00:43	1	0,36	Versandt
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Di. 14.09.2004, 12:46:15	00442077242632		Scan	12:46:26	01:19	1	0,12	Versandt



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,406	12/20/2001	Dirk Nehring		5065

7590 05/20/2005  
deltaT GmbH  
Kerkrader Strasse 11  
Hessen, 35394  
GERMANY

EXAMINER

SODERQUIST, ARLEN

ART UNIT PAPER NUMBER

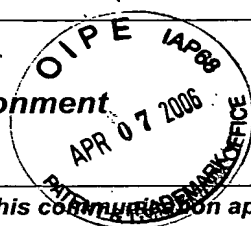
1743

DATE MAILED: 05/20/2005

EINGEGANGEN AM 31. MAI 2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Notice of Abandonment**



Application No.

10/022,406

Examiner

Arlen Soderquist

Applicant(s)

NEHRING ET AL.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 23 June 2004.
  - (a) ☐ A reply was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.
  - (b) ☐ A proposed reply was received on \_\_\_\_\_, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.  
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
  - (c) ☒ A reply was received on 20 September 2004 but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
  - (d) ☐ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
  - (a) ☐ The issue fee and publication fee, if applicable, was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
  - (b) ☐ The submitted fee of \$\_\_\_\_\_ is insufficient. A balance of \$\_\_\_\_\_ is due.  
The issue fee required by 37 CFR 1.18 is \$\_\_\_\_\_. The publication fee, if required by 37 CFR 1.18(d), is \$\_\_\_\_\_.
  - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
  - (a) ☐ Proposed corrected drawings were received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply.
  - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☒ The reason(s) below:

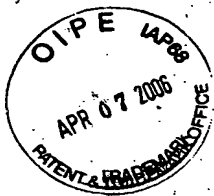
Applicant has failed to correct the deficiencies noted in the of notice of fee deficiency, mailed September 24, 2004.

*Arlen Soderquist*

ARLEN SODERQUIST  
PRIMARY EXAMINER

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.





delta T GmbH Kerkraeder Strasse 11 D-35394 Giessen

FAX TO: Mr. Arlen Soderquist  
FAX No. 001 703 872 93 06  
FROM: Mr Dirk Nehring (total 23 pages)  
Application Number: 10/022,406  
Applicants: Nehring ET AL  
Art Unit: 1743

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Dear Mr Soderquist

Thank you for your correspondence regarding the above US patent application and the reasons why it has initially been rejected.

Regarding the disposition of the claims; Claims 1 to 19 have initially been rejected. We have revised these as you correctly pointed out that as originally written, in the most part it seems obvious to one of ordinary skill in the art of the time of the invention, given the previous US Patents cited by you, that the invention could have been arrived at. We have addressed each of these patents as follows;

In U.S. Pat. No. 5,235,819 an apparatus for storing and distributing materials is described.. The apparatus maintains products at an intended temperature during transporation and storage at an ambient temperature deviating from the intended temperature. The invention features a container that holds the products and whose walls render heat transfer difficult. The container includes a main container body with a bottom and a side section that together define one or more integrated compartments suitable for storing a solidifiable substance.

The invention does not consist of modular identical halves or frame structures that may be stacked on top of each other to create a flexible, modular system enabling variable inner volumes to suit different product sizes, thus maximising the inner volume for the amount of product being stored whilst also being completely surrounded by the temperature-regulating fluid. The fact that this transport apparatus is not modular makes it impossible to transport variable volumes of products such as medications, blood and organs, which are the intended products to be transported in the system invented by Nehring and Bienert.

An insulated modular cooler comprising in one embodiment a plurality of tubular housing sections and a plurality of tubular hollow-walled insert housing containing a refrigerant in the hollow walls of the insert housings was invented by Basso (4,517,815). The tubular housing sections can be secured end to end to form an elongated tubular hosing. However, the tubular system has to have an end cap to secure the product being transported inside, which functions like a thermal bridge so that heat from the outside can be easily conducted into the inner compartment of the tubular housing. There is no cooling fluid within this end cap, which

means that the cooling fluid does not surround the entire inner compartment. Furthermore, another bottom cap is required to close the system. The temperature stability of the product to be transported is less therefore predictable because the cooling fluid does not surround the inner compartment completely. The invention does not consist of modular identical halves that may be stacked on top of each other, which require neither an end or bottom cap as is the case in this Nehring and Bienert invention, whereby the product being transported is totally surrounded by temperature regulating fluid.

A combination dental material mixing slab holder and cooler which includes a base plate having a pair of spaced, upwardly projecting ribs and a central well was invented by Drake (3,858,410). This patent teaches that the heat sink means it is a stable liquid or solid material, having a relatively high latent or heat capacity. However, no modular dispositions are explained and the cooling liquid or solid material does not surround the inner compartment completely. The temperature profile through the cross sections is inhomogeneous due to the different conductivity of the lid and the container itself.

Various phase change formulations usable in thermal packaging systems using a single phase change material part in liquid and part in solid form to confine the temperature of the product within a predetermined range was described by Malach (6,482,332). The temperature ranges are determined by selection of the phase change material. Blends such as butandiol, selected amounts of distilled water and nucleating agents can be formulated to achieve phase changes from +40° to -30°C. However Malach does not describe a modular system or a double walled apparatus that surrounded the inner compartment completely by phase change material. Furthermore the construction of the described container requires an end cap and a bottom cap for closure.

Sheehan invented a portable cooler for use in transporting medicines including an insulative housing containing a coolant (4,322,954). One compartment is made for a coolant and the other for the product. A heat tube connects both compartments. The device includes a carrying strap and latches. The device is not constructed like a modular expandable system and the cooling liquid or material does not directly or completely surround the product to be transported.

MacDonald teaches in patent (5,058,397) a cryogenic storage container for biological specimens that include a cooling gel or medium to keep the specimens at a low temperature. The storage box includes a rectangular housing having a chamber filled with a coolant gel, and a plurality of spaced, tube supporting wells opening at their upper ends. A cover, which is connected to the housing, contains a sealed envelope containing coolant gel. The device includes hinges and latches, but does not consist of a modular system that surrounds the inner volume completely.

Schea (5,181,394) disclosed a shipping unit for containers of liquid compositions, such as solutions of biologically active proteins. A phase change material such as carboxymethylcellulose gel is disposed in the enclosed space between sidewalls and maintains the temperature of the inner containers. A freeze indicator provides an irreversible visual signal upon reaching a temperature intermediate the nucleation temperature of the liquid composition and the freezing temperature of the phase change material. Thus thermocouple devices of varying kinds and simple devices such as described in U.S. Pat. Mo. 4,191,125 are quite suitable as the freeze indicators. However, the device of Schea can not be used as a modular system to increase the inner volume and it is not constructed to surround an inner compartment by phase change material to avoid heat bridges.

Since it would be obvious to one of ordinary skill in the art that complete surrounding of the inner compartment enhances the temperature stability of the inside product it is not obvious for one of ordinary skills to combine both features of modularity and the complete surrounding of phase change material and also construct this by avoiding a double walled system without an end cap or bottom cap.

Regarding the application papers the drawings have also been revised to show in more clarity the parts of the invention and their pertinance to it. We have paid particular note to your comment ( "It is not clear what structure consitutes a clip"). We have revised this to rename the "clip" as "notches and indentations" as they are notches and indentations moulded into the system (Fig 1 shown as 11 and 2). Furthermore the structure names as "ring" (figure 3; 20) was renamed as "double wall frame".

The certified copies of the prior European Patent 0124070.2 have been requested from the European Patent offices and will be sent to you as soon as we receive them.

We trust that our amendments explain the points you made in full. We are aware that your time is limited, so should you require any further assistance whilst processing our US Patent application, you may contact us by email at [info@deltaT.de](mailto:info@deltaT.de) and we will answer you promptly or call you if you prefer.

Kind regards

  
Dirk Nehring

## **Transport Systems For Products at Consistent Temperatures**

A system to transport goods at consistent temperatures.

### **Abstract**

The invention is a system for the transport of products at a consistent temperature by use of a protective container for fragile products, specifically a container that protects and transports blood and medical products, with properties described in the detailed description section of this Patent Application.

Inventors: **Nehring; Dirk** (Langgoens, Germany); **Bienert; Kai** (Giessen, Germany)

**Current U.S. Class:**

**62/457.9; 62/235.1; 62/236**

**Intern'l Class:**

**F25B 027/00; F25B 021/00**

**Field of Search:**

**62/371,457.9, 457.7,235.1,238.1,236,457.1,457.2, 252/67**

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#### *Claims*

What is claimed is:

1. A system comprising a rectangular double walled container filled with temperature-regulating fluid to maintain consistent temperatures designed to contain store and label perishable goods, such as blood products, antibodies, cells or biologically produced pharmaceuticals comprising:
 

two identical halves, which may be securely closed together to create a sealed single module, or, may be stacked on top of each other, with or without the addition of complimentary double walled extension frames, both of which create a flexible, modular system enabling variable inner volumes to suit different product sizes, thus maximising the inner volume for the amount of product being stored;

the geometry of the system allows the product being stored or transported to be completely surrounded by the temperature-regulating fluid and each identical half provides temperature regulating properties and acts as a first end cap or bottom end cap.

a modular system allowing the user to determine the inner volume to suit the amount of product to be transported and the volume of the temperature regulating fluid, which in turn determines the period at which the temperature regulating fluid maintains temperature consistency.

2. The system according to claim 1, is thus characterised as the container is made up of two double walled halves which can be attached together by notches and indentations along the longest sides of it.
3. The system according to claim 1, is thus characterised as the container is made up of two double walled halves and also a double walled complimentary frame, which can be attached together by notches and indentations along the longest sides of it.
4. The system according to claim 1, is thus characterised as the container is filled with paraffin or a carrier immobilised paraffin as a temperature regulator.
5. The system according to claim 4, is thus characterised as the paraffin shows a condition between fluid and solid at temperatures between 2° C and 8° C or 20° C and 24° C.
6. The system according to claim 4, is thus characterised as above 0° C n-hydrocarbons can be used, namely n-paraffins with the formula  $C_nH_{2n+2}$ .
7. The system according to claim 1, is thus characterised as the container is filled with a watery saline solution or an ethanol-water mix as a temperature medium which has a consistency between fluid and solid at temperatures between -20° C and -40° C.
8. The system according to claim 1, is thus characterised as the container is filled with a buthandiol water mix as a temperature medium which has a consistency between fluid and solid at temperatures between 20°C and 24°C.
9. The system according to claim 1, is thus characterised as the double wall is transparent, specifically made from a transparent plastic.
10. The system according to claim 1, is thus characterised as the double wall is made from an impervious plastic such as Kevlar, or from metals such as aluminium or iron.
11. The system according to claim 1, is thus characterised as the double wall has an outside locking mechanism.
12. The system according to claim 2, is thus characterised as the container consists of two double walled halves which can be sealed along the longer sides with a clip.
13. The system according to claim 3, is thus characterised as the container consists of two double walled halves and a complemetary double walled frame which can be sealed along the longer sides with a clip.
14. The system according to claim 11 or 12, is thus characterised as the container is fitted with an eyelet which allows for sealing.

15. The system according to claim 2, is thus characterised as the container made from two double walled halves that are fitted with tongues and grooves along the longer sides.
16. The system according to claim 2, is thus characterised as the container made from two double walled halves and a complementary double walled frame that are fitted with tongues and grooves along the longer sides.
17. The system according to claim 2 or 3, is thus characterised as the container made from two double walled halves and/or a complementary double walled frame are attached with a moveable hinge.
18. The system according to claim 2 or 3, is thus characterised as the container has a carrying strap.
19. The system according to claim 2 or 3, is thus characterised as the container made from two or three complementary double walled halves which enclose a space intended to store products is fitted with a thermometer, specifically a self adhesive strip thermometer or a liquid crystal thermometer and/or an electronically readable temperature guage.

## **Description**

### **BACKGROUND OF THE INVENTION**

The transport and storage of blood products requires a consistent cool chain in the temperature ranges of 2 to 6°C, < -20°C and between 20° to 24°C in order to maintain its life giving properties. To satisfy these requirements, blood products are transported in temperature regulated containers which are either passively cooled by means of accumulators or by active electrical cooling methods.

Such transportation containers are extensively used in the professional transportation of blood. A weakness in existing transport systems is however, in the un- and reloading of blood products, as they are passed over to the reciever in containers with only short term isolation properties. The adherence to the cool chain is, in such cases, mostly not quantifiable and the period in which the required temperatures are maintained is very short.

A further problem is with the internal transport in clinics. Blood products that, for example, leave storage in preperation for the operation theatre, are not kept under temperature control as they are presently transported in simple insulated containers. If this blood product is then not used, it is not quantifiable whether the permitted temperature levels have been exeeded. In order to save and re-store this blood a complicated and extensive analytical test must be undertaken. Furthermore, most containers used to transport blood do not have any protective mechanism against tampering.

In order to create a cool chain, previous methods used to transport temperature sensitive products at the required temperature levels have been to use insulated chambers (i.e. boxes) that has an insulated inner layer together with a simple cooling device that is filled with a liquid of high specific enthalpy. A disadvantage in using this method is however, that the liquid with high specific enthalpy comes into direct contact with the packaging in which the blood is kept and adherence to the required temperature levels is not visible from the outside. Furthermore, the thermal enthalpy of the fluid is not effective enough.

In U.S. Pat. No. 5,235,819 an apparatus for storing and distributing materials is described.. The apparatus maintains products at an intended temperature during transporation and storage at an ambient temperature deviating from the intended temperature. The invention features a container that holds the products and whose walls render heat transfer difficult.



The container includes a main container body with a bottom and a side section that together define one or more integrated compartments suitable for storing a solidifiable substance.

The invention does not consist of modular identical halves or frame structures that may be stacked on top of each other to create a flexible, modular system enabling variable inner volumes to suit different product sizes, thus maximising the inner volume for the amount of product being stored whilst also being completely surrounded by the temperature-regulating fluid. The fact that this transport apparatus is not modular makes it impossible to transport variable volumes of products such as medications, blood and organs which are the intended products to be transported in this present invention.

An insulated modular cooler comprising in one embodiment a plurality of tubular housing sections and a plurality of tubular hollow-walled insert housing containing a refrigerant in the hollow walls of the insert housings was invented by Basso (U.S. Pat. No. 4,517,815). The tubular housing sections can be secured end to end to form an elongated tubular housing. However, the tubular system has to incorporate an end cap to secure the product being transported inside, which functions like a thermal bridge so that heat from the outside can be easily conducted into the inner compartment of the tubular housing. There is no cooling fluid within this end cap which means that the cooling fluid does not surround the entire inner compartment. Furthermore, another bottom cap is required to close the system. The temperature stability of the product to be transported is therefore unpredictable because the cooling fluid does not surround the inner compartment completely. The invention does not consist of modular identical halves that may be stacked on top of each other and which require neither an end or bottom cap as is the case in this present invention, whereby the product being transported is totally surrounded by temperature regulating fluid.

A combination dental material mixing slab holder and cooler which includes a base plate having a pair of spaced, upwardly projecting ribs and a central well was invented by Drake (U.S. Pat. No. 3,858,410). This patent teaches that the heat sink means it is a stable liquid or solid material, having a relatively high latent or heat capacity. However, no modular dispositions are explained and the cooling liquid or solid material does not surround the inner compartment completely. The temperature profile through the cross sections is inhomogeneous due to the different conductivity of the lid and the container itself.

Various phase change formulations usable in thermal packaging systems using a single phase change material part in liquid and part in solid form to confine the temperature of the product within a predetermined range was described by Malach (U.S. Pat. No. 6,482,332).

The temperature ranges are determined by selection of the phase change material. Blends such as butandiol, selected amounts of distilled water and nucleating agents can be formulated to achieve phase changes from +40° to -30°C. However Malach does not describe a modular system or a double walled apparatus that surrounded the inner compartment completely by phase change material. Furthermore the construction of the described container requires an end cap and a bottom cap for closure.

Sheehan invented a portable cooler for use in transporting medicines including an insulative housing containing a coolant (U.S. Pat. No. 4,322,954). One compartment is made for a coolant and the other for the product. A heat tube connects both compartments. The device includes a carrying strap and latches. The device is not constructed like a modular expandable system and the cooling liquid or material does not directly or completely surround the product to be transported.

MacDonald teaches in patent (U.S. Pat. No. 5,058,397) a cryogenic storage container for biological specimens that include a cooling gel or medium to keep the specimens at a low temperature.

The storage box includes a rectangular housing having a chamber filled with a coolant gel, and a plurality of spaced, tube supporting wells opening at their upper ends. A cover, which is connected to the housing, contains a sealed envelope containing coolant gel. The device includes hinges and latches, but does not consist of a modular system that surrounds the inner volume completely.

Schea (U.S. Pat. No. 5,181,394) disclosed a shipping unit for containers of liquid compositions, such as solutions of biologically active proteins. A phase change material such as carboxymethylcellulose gel is disposed in the enclosed space between sidewalls and maintains the temperature of the inner containers. A freeze indicator provides an irreversible visual signal upon reaching a temperature intermediate the nucleation temperature of the liquid composition and the freezing temperature of the phase change material. Thus thermocouple devices of varying kinds and simple devices such as described in U.S. Pat. No. 4,191,125 are quite suitable as the freeze indicators. However, the device of Schea cannot be used as a modular system to increase the inner volume and it is not constructed to surround an inner compartment by phase change material to avoid heat bridges.

Another further problem is that all of the described systems do not provide complete surrounding with the phase change material causing an unpredictable inner temperature alteration due to heat bridges. When the inner compartment of a container is surrounded completely in a homogenous manner the inner temperature is fully controlled by the phase

change allowing a maximum transport time to be achieved with predictable temperature values.

Since it would be obvious to one of ordinary skill in the art that complete surrounding of the inner compartment enhances the temperature stability of the inside product it is not obvious for one of ordinary skills to combine both features of modularity and the complete surrounding of phase change material and also construct this by avoiding a double walled system without an end cap or bottom cap.

The purpose of this invention is to provide a transport system for products at consistent and predictable temperatures, specifically blood and medical products, which hinders tampering of single or multiple units and maintains the permitted temperatures. A further purpose of this invention is to show on the container whether the permitted temperatures have been maintained.

The solution is found with a system to transport products at consistent temperatures, specifically the temperature regulated transport of blood and medical products with the properties according to claim 1. Advantageous properties of the invention are described in fully in the claim.

#### **SUMMARY OF THE INVENTION**

In accordance with the invention the system, a storage, protection and transport container for easily perishable products, made from double walls that are filled with a fluid or solid latent temperature regulating fluid to give it insulating properties, enables the transport of products at consistent temperatures, especially to transport blood and medical products.

A major property of the invention is that the container, consisting of two identical halves (1) and (10) or frames (20) that close together, snap tightly shut due to a series of notches (11) and indentations (2) along the perimeter of each half or frame. When the two halves are closed together a protective space (3) is created within, which enables the storage of blood and/or pharmaceuticals. The construction of the identical halves allows the product being stored or transported to be completely surrounded by the temperature-regulating fluid. Furthermore, each identical half (1; 10) provides temperature-regulating properties and acts as a first end cap or bottom end cap.

The storing, protection and transporting system of the present invention comprises:

- (1) Two double walled halves (1 and 10) with notches (11) and indentations (2) along the perimeter edges (5 and 6) that allow them to fit tightly together and create an inner space (3) for the storage and transport of blood, blood products (30) or pharmaceuticals.
- (2) A double walled frame (20) with notches (11) and indentations (2) along the perimeter edges (4) that allow it to fit tightly together with the two other halves (1) to create a larger inner space for the storage of blood, blood products (30) or pharmaceuticals.
- (3) A contained latent temperature regulating fluid (in each half and frame), specifically paraffin, or a carrier immobilised paraffin, or a saline solution, or an ethanol water mix or a buthandiol water mix which provide a plateau of constant temperatures of -20°C to -40°C, 2°C to 6°C and 20°C to 24°C.
- (4) Eyelets (9) on each half (1) which allow the container to be sealed with a lead seal to stop undesired or at least recognisable opening of the container
- (5) Indentations (14) on each half to allow for a carrying strap to be fitted.
- (6) A sealed opening on each half (12) to allow them to be filled with the latent temperature regulating fluid.
- (7) Each half is fitted inside with a thermometer (34), specifically a self-adhesive strip thermometer or a liquid crystal thermometer and/or an electronic readable temperature gauge.

#### DESCRIPTION OF THE DRAWINGS

Other properties, peculiarities and advantages of the invention are shown in diagrammatical form and described as follows:

Fig. 1: an innerview perspective of the storage, protection and transport container according to the invention.

Fig. 2: an outer view perspective of the part shown in Fig. 1 of the storage, protection and transport container according to the invention.

Fig. 3: a perspective view of the frame that fits together with the parts in Fig.1 and Fig.2 of the storage, protection and transport container according to the invention.

Fig. 4: a perspective outer view of the storage, protection and transport container that consists of the parts of Fig. 1, Fig.2 and Fig. 3 according to the invention.

Fig.5: a perspective view of a single half (1) combined with frames (20) that fit together and form a storage, protection and transport container according to the invention.

Fig 6: two schematic cross sections of two identical halves (1) containing one or two blood product units (30) depending on the addition of a double walled frame (20) to extend the inner volume according to the invention.

Fig. 1: The system to transport products at consistent temperatures consists of two identical halves, shown in Figure 1 and Figure 2. Fig. 1 shows an innerview perspective of one half. This half (1) can be locked together with a second same half (10) by means of notches (11) and indentations (2). The first half locked together with a second half creates an inner space (3), which is completely shielded from the outside elements due to the double walls of the two halves (1 and 10) and the tongues (4) and grooves (5) along the connecting edges (6) of the container. This space (3) allows for the storage of blood products (shown in Fig. 6) or other products such as antibodies, cells or pharmaceuticals in their original packaging.

Fig. 2: The outer view perspective of one half is shown in Fig. 2. The halves (1 and 10) contain a liquid or solid temperature-regulating medium within the double walls and have sealable openings (12) to fill them. The parts have indentations (14) on the outside to fit a carrying strap and protrusions (7) and indentations (8) to enable them to lock snugly together and allow for stacking. With the aid of a sealing tie (not shown) both parts can be sealed together.

Fig. 3: Respective characteristics are marked in Fig.1 and 2. A double walled frame (part 20) fits together with parts 1 and 10 by means of notches (11) and indentations (2) along the connecting edges (6) thus increasing the interior volume.

Fig. 4: Respective parts are marked in Fig.1, 2 and 3. The system used to transport products at consistent temperatures with improved protection and storage is achieved by fitting a half (1) together with a second same half (10) and a frame (20) which fits between both halves by means of notches (11) and indentations (2). The identical halves (1 and 10) are featured with an eyelet (9) on both sides that allows sealing of the whole container.

Fig. 5: Respective parts are marked in Fig.1, 2 and 3. The inner volume (3) can be increased by stacking a single or chosen multiples of frames (20) to create a modular system, whereby

the user can self determine the inner volume (3) that is required to store or transport the product. Two identical halves (1) not only provide temperature insulation for the product(s) but also create a bottom end and top end cap that closes the container, whilst also totally encompassing the product homogenously with temperature regulating fluid. The frames and halves lock tightly together by means of notches (11) and indentations (2).

Fig 6: Respective parts are marked in Fig. 1, 2 and 3. The system to transport products at consistent temperatures is shown in a schematic cross section. The two identical halves can be equipped with an carrying strap (32) or an liquid crystal thermometer (34) and form an inner volume (3) that can be used to store one or more blood products (30). The inner volume of the structure can be expanded by attaching frames (20). Moreover, by choosing the number of frames used (20) not only is the inner volume thus determined but also the total amount of phase change material (the more frames used, the greater the volume of phase change material and thus also the length of transportation time (the greater the volume of phase change material, the longer the transportation time).

The double wall of parts (1; 10; 20) all have sealable openings (12) which enable filling or emptying with a latent temperature regulating fluid, specifically paraffin or a carrier immobilised paraffin or a buthandiol water mix, a watery salt mix or an ethanol water mix, which has a melting point of either 20 to 24° C, 2 to 6° C, -20 to -30° C and -20 to -40° C. Alternatively, n-paraffins with the formula  $C_nH_{2n+2}$  can be used to stabilise temperatures above 0° C.

The transparent walls of the storage, protection and transport container (1; 10; 20) enables one to see the condition of the temperature regulating fluid and that the required temperatures have been adhered to. In this way blood products such as erythrocyte concentrates and thrombocytes can easily be transported and handled at temperatures of 2 to 6° C and 20 to 24° C.

The container, made up of two (Fig. 6) or the three (Fig. 4) double walled parts which fit together to create an inner space for the products (30) in which the temperature should remain constant, is fitted with a thermometer (34), specifically a self adhesive strip thermometer, a liquid crystal thermometer and/or an electronic readable temperature gauge which can be set to read -temperatures of 20 to 24° C, 2 to 6° C, -20 to - 30° and -20 °C to - 40 °C.

The container, made up of two or three complimentary double walled parts each have at least one eyelet (9) which allows the halves to be sealed together with a led seal, to prevent or show any undesired opening of it as shown in Fig. 4.

#### DETAILED DESCRIPTION OF THE INVENTION

In accordance with the invention the system, a storage, protection and transport container for easily perishable products, made from double walls that are filled with a fluid or solid latent temperature regulating fluid to give it insulating properties, enables the transport of products at consistent temperatures, especially to transport blood and medical products.

A major property of the invention is that both identical halves (Fig 1 and 2) that fit together are double walled, which together with a similarly produced frame (Fig 3) that also snaps with its notches (11) onto the indentations (2), increases the protective storage space (3) between them. In this way, the one half serves as the top (10) and the other as the bottom (1) of the container (Fig. 4 and Fig. 6), thus the system does not require an extra lid and the product being stored or transported within the system is completely surrounded by the temperature regulating fluid that is held between the double walls. The double walled frame (20) is also filled with a liquid, which according to the energy applied to it, may be charged with or emit a required temperature. These double walled halves and frames filled with the temperature regulating fluid can be fitted together in such a way, so that a modular system is created, whilst the inner volume can also be varied depending on the number of frames used (Fig 5 and Fig. 6), providing an inner volume space (3) of between 250ml and 100 litres.

Another major property of the invention is that the container, consisting of two identical halves that close together, snap tightly shut due to a series of notches (11) and indentations (2) along the perimeter of each half (Fig 1, 2 and 3). When the two halves are closed together a protective space (3) is created within, which enables the storage of blood and/or medical products.

Another property of the invention is that the double wall of each part is filled with a latent temperature regulating fluid which has a melting point of 2 to 6° C, specifically paraffin or a carrier immobilised paraffin, which maintains the temperature of the storage space within at a consistent temperature of 2 to 6° C. The container is therefore capable of storing and transporting erythrocyte concentrates and other blood products, antibodies, cells or biotechnically produced pharmaceuticals which have to be transported at 2 to 6° C.

Another property of the invention is that n-hydrocarbons, namely n-paraffins with the formula  $C_nH_{2n+2}$  can be used to stabilise temperatures above 0 °C.

Another property of the invention is that the container is filled with a saline solution or an ethanol water mix that has a consistency between fluid and solid between the temperatures of -20 °C and -40 °C.

Another property of the invention is that the double wall of the container is filled with a latent temperature regulation fluid which has a melting point of 20 to 24° C, specifically paraffin Or a carrier immobilised paraffin or a butanol water mix in order to keep the inner storage space at a constant temperature of 20 to 24° C. The container is therefore capable of storing and transporting thrombocytes and other blood products that have to be transported at these temperatures.

Another property of the invention is that the material from which the double walled container is produced is transparent, specifically a transparent plastic, so that the condition of the temperature regulating fluid within is visible. It is therefore easy to check the temperature levels making the container useful for cool chain transportation.

Another property of the invention is that the double walled half is produced from impervious plastics such as polyamid e.g. kevlar, or from metals such as aluminium, steel or iron.

Another property of the invention is that the containers may be stacked as there are protrusions (7) and indentations (8) on the back of the container allowing for this as shown in Fig. 2.

Another property of the invention is that there are two closures attached to the transport container that are sealable.

Another property of the invention is that the container is fitted with at least one eyelet (9) which can be sealed so that undesired opening can be avoided or is at least recognisable as indicated in Fig. 4.

Another property of the invention is that the parts of the storage, protection and transport container are fitted with tongue and groove (4 and 5) to avoid temperature loss as shown in Fig. 1.



Another property of the invention is that the parts of the storage, protection and transport container are connected by a hinge.

Another property of the invention is that the container may be fitted with a carrying strap.

Another property of the invention is that the container is fitted inside with a thermometer (34), specifically a self sealing strip thermometer or a liquid crystal thermometer and/or an electronic readable temperature gauge as schematically indicated in Fig. 6.

Fig. 1

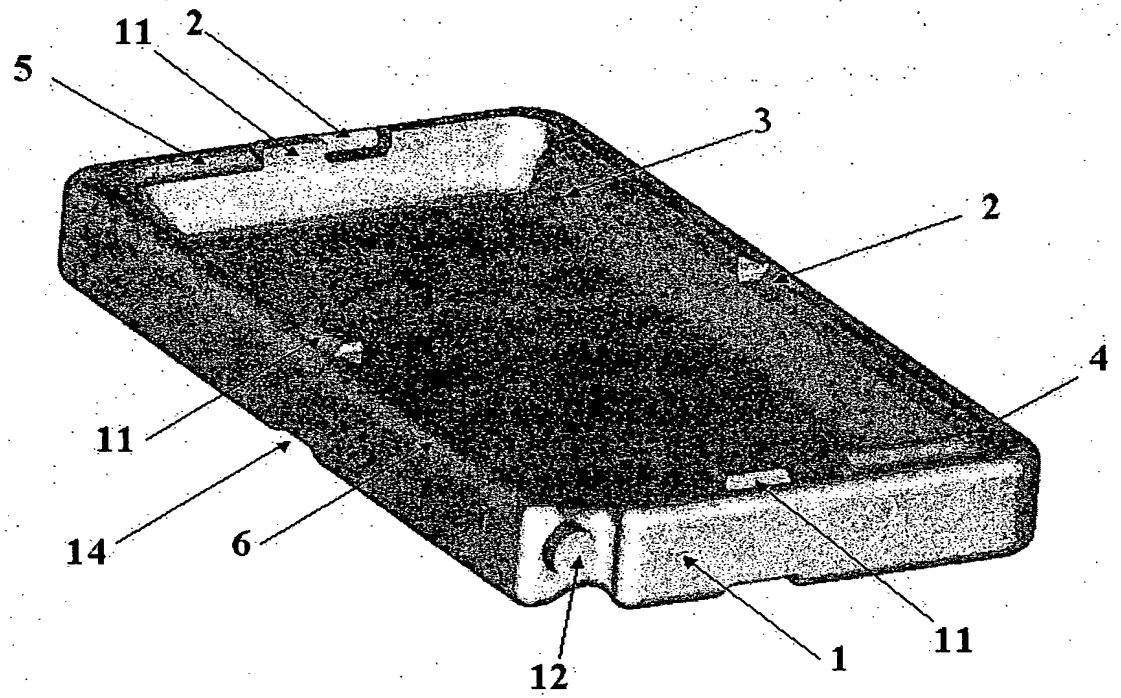




Fig. 2

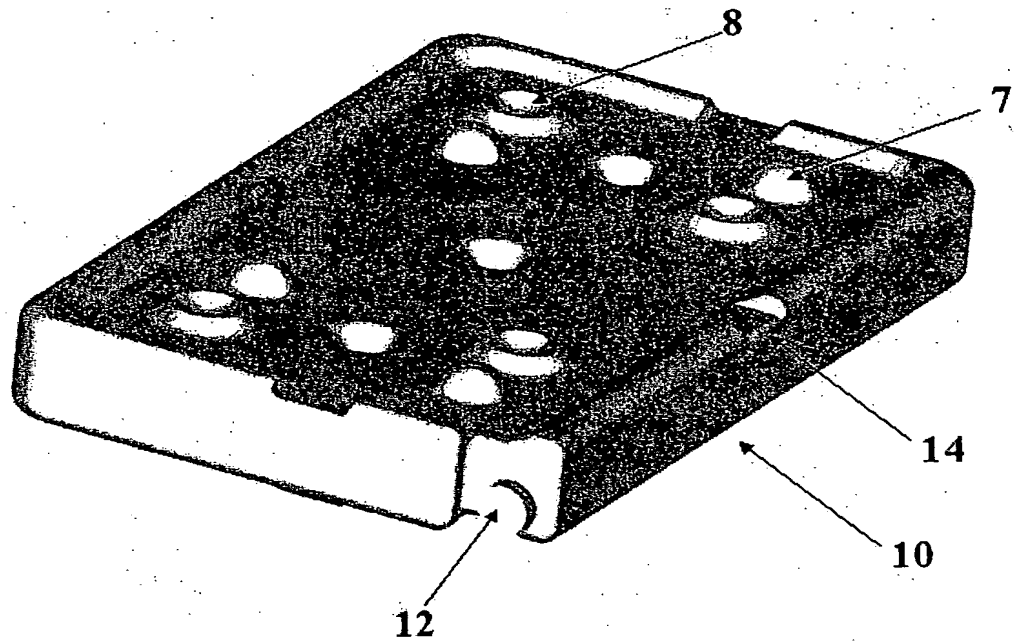


Fig. 3

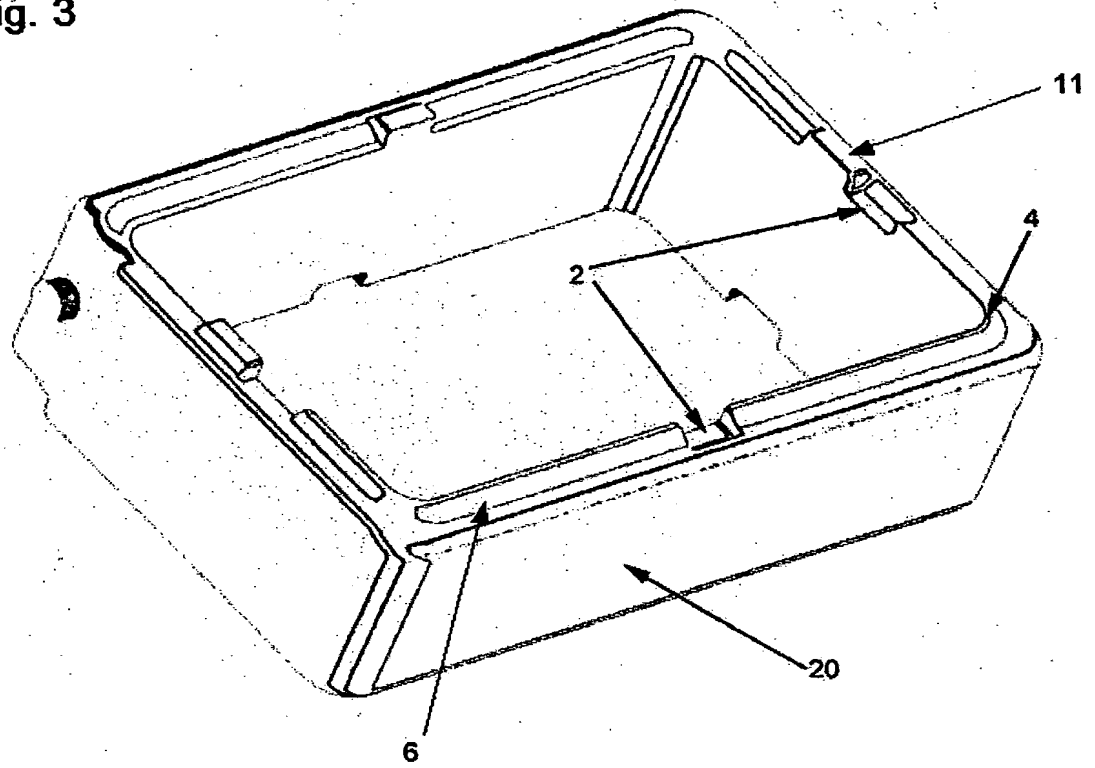


Fig. 4

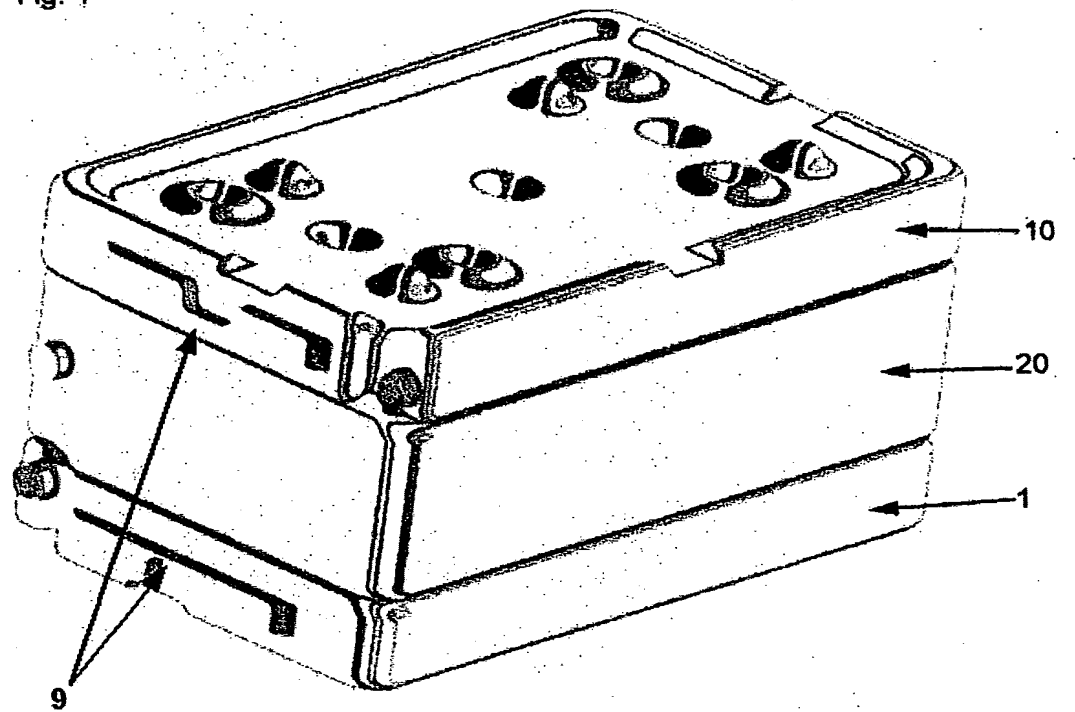


Fig. 5

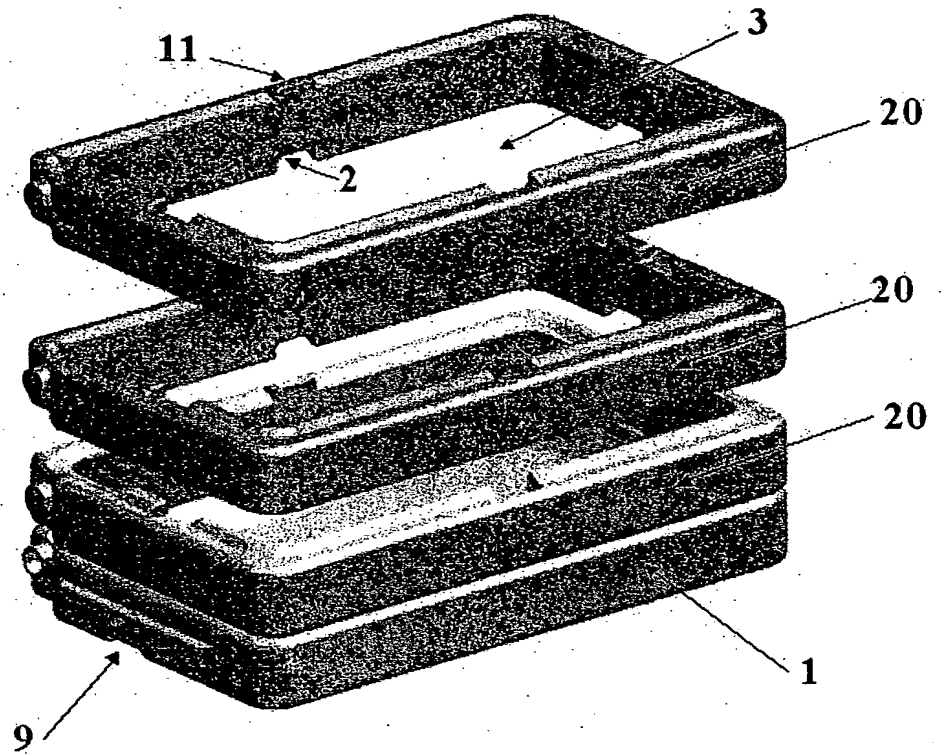


Fig. 6

